



10-09-03

1614

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (PATENT)

Application of: **Alan J. Mautone**

Serial No. :10/608,166

Group Art Unit: **1614**

Filed :

Examiner: D. Jagoe


For : **COMPOSITION AND METHOD
FOR TREATMENT OF OTITIS MEDIA**

Att. Docket :

TRANSMITTAL LETTERCommissioner for Patents
PO Box 1450
Arlington, Virginia 22313-1450
Sir:

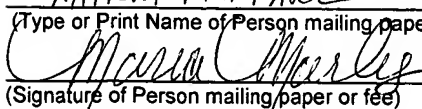
Enclosed herewith is Applicant's Information Disclosure Statement in accordance with 37 C.F.R. 1.56/1.97 , PTO Form 1449, the copies of the cited references and a self-addressed postage paid postcard as and for documentation of the receipt of the foregoing documents by the office of Commissioner for Patents.

Respectfully Submitted


34,445
Richard L. Strauss (Reg. No.)

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MARIA MARTINEZ
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Patent)

Application No.: 10/608,166

Class (Prel.): 1614

Filed: 06/27/03

Examiner: D. Jagoe

Inventor: Alan J. Mautone

Title: COMPOSITION AND METHOD FOR
TREATMENT OF OTITIS MEDIA

Att. Docket:

**INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE
WITH 37 C.F.R. 1.56/1.97**

Commissioner of Patents
PO Box 1450
Arlington, Virginia 22313-1450
Sir:

In accordance with the requirements of 37. C.F.R. 1.56/1.57, the following information and references are presented in regards to the above-identified application.

US Patent No. 4,814,161 - (" The '161" patent) Inventor - Philip A. Jinks and Alexander Bell. The '161 patent discloses the complete dissolution of a wide range of drugs in chlorofluorocarbon aerosol propellants in the presence of glycerol phosphatides, preferably phosphatidylcholine.

US Patent No. 4,895,719 - (" The '719" patent) Inventor - Ramachandran Radhakrishnan. The '719 patent discloses a system and method for administering a

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MARIA T. MARTINEZ

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Maria T. Martinez
(Signature of Person mailing paper or fee)



ing, at a selected dose, via the respiratory tract. Spray-dried liposome particles containing the selected dose of the entrapped drug are released into the air in aerosolized form, either by entrainment in an air or propellant stream, or be release from a pressurized can containing a suspension of the liposomes in a fluorochlorocarbon solvent.

US Patent No. 4,931,284 - (" The '284" patent) Inventor - Bo Em Ekman, Kare V. Larson, Ake R. Kindahi, et al. The '284 patent discloses a micro-capsule composition consisting essentially of a hydrophilic lipophilic substance surrounded by surface-active solid crystals of polar lipids, which crystal have a hydrophilic side that is exposed outwards and a hydrophobic side that is turned inwards toward the hydrophobic or lipophilic substance.

US Patent No. 4,973,465 - (" The '465" patent) Inventor - Roger Baurain and Andre B.L. Troust. The '465 patent discloses microcrystals of a substance which is insoluble in water and has an affinity for phospholipids as well as a process for preparing same.

US Patent No. 5,004,611 - (" The '611" patent) Inventor - Steven Leigh. The '611 patent discloses pro-liposome compositions comprising membrane lipids such as lecithin or distearyl dimethylammonium chloride, water-miscible solvents such as ethanol, optionally a minor proportion of water, and optionally fatty acid esters and drugs.

US Patent No. 5,053,217 - (" The '217" patent) Inventor - Steven Leigh. The '217 patent discloses pro-liposome compositions comprising membrane lipids such as lecithin or distearyl dimethylammonium chloroide, water-miscible solvents such as ethanol, optionally a minor proportion of water, and optionally fatty acid esters and drugs.

US Patent No. 5,141,674 - ("The '674" patent) Inventor - Leigh. The '674 patent discloses compositions that are sprayable or that are in the form of discrete particles and that contain a lipid and a biologically active compound in the form of a



micronized powder combine a high initial entrapment of the active compound in the membrane lipid with sustained release at the site of application as indicated by in-vitro and in-vivo tests.

US Patent No. 5,174, 988 * - (" The '988" patent) Inventors - Alan J. Mautone and Joel Klayman, discloses a process for preparing lipid crystals in combination with a therapeutically active substance comprising (a) admixing dipalmitoylphosphatidyl choline, one of the group of phospholipids known as fully saturated acyl chain phosphatidylcholines, and cholesteryl palmitate, in powder form, with a therapeutically active substance and one or more fluorocarbon propellants, the lipids being insoluble in the propellants, and (b) evaporating the propellants. The 988 patent discloses and suggests the use of the above-described lipid crystals as a carrier for therapeutically agents effective in the treatment of pulmonary conditions such as albuterol and pilocarpine. The patent teaches discloses and suggests the use of said mixture in the treatment of pulmonary applications and an artificial tear.

US Patent No. 5,306,483 *- (" The '483" patent) Inventor - Alan J. Mautone. This patent, originally filed as a continuation-in-part of app. No.385,907, ((the application from which the '988 patent issued) contains substantially discloses substantially the same lipid crystalline mixture as disclosed by the '988 patent. However, the claimed propellants in the '483 patent include the more "environmentally friendly" chlorofluorocarbons, hydrofluorocarbons or mixtures thereof. Similar to the '988 patent, the '483 patent teaches discloses and suggests the use of said mixture in the treatment of pulmonary applications and an artificial tear.

US Patent No. 5,401,741 - (" The '741" patent) Inventor - Kiichi Sato, Akira Handa, Takeji Kitahara. The '741 patent discloses a topical preparation for treating otophathy which contains ofloxacin or a salt thereof as an active ingredient.

US Patent No. 5,470,587 - (" The '587" patent) Inventor - Inventor Joseph R. Di Bartolomeo. A composition and method for the treatment of patulous eustachian tube syndrome and atrophic rhinitis is disclosed wherein a solution comprised of hydrochloric acid, benzyl alcohol, and chlorobutanol, which may be dissolved in



propylene glycol, and a pharmaceutically acceptable liquid carrier is applied topically, to the nasal mucosa intra-nasally in the form of drops, nasal spray or aerosol.

US Patent No. 6,001,870 - ("The '870" patent) Inventor - Timothy John Henkyl. The '870 patent discloses Mupirocin or a salt or ester thereof utilized as a treatment for recurrent sinusitis and recurrent otitis, in particular with novel spray or cream formulations for administration to the nasopharynx.

US Patent No. 6,093,417 - ("The '417" patent) Inventor - Petrus. The '417 patent discloses a topical ear composition that uses penetration enhancers to diffuse the therapeutic agents through the tympanic membrane into the middle and inner ear for the purpose of reducing the inflammation of ear tissues, providing pain relief, and introducing agents with antimicrobial activity to combat infection.

US Patent No. 6,156,294 - ("The '294" patent) Inventor - Alan J. Mautone. The '294 patent discloses a method of increasing and enhancing mammalian eustachian tube lumen patency and pressure equalization performance by administering an aerosolized mixture of lipid crystals comprised of a mixture of one or more lipid surfactants and one or more spreading agents, in powdered form, and one or more fluorocarbon propellants through a mammalian nasal orifice.

US Patent No. 6,297,227 - ("The '227" patent) Inventors - Johnson. The '227 patent discloses antibiotic-excluded compositions and methods to treat non-infective sinusitis and otitis media. The compositions comprise a therapeutically effective amount of a corticosteroid, and the methods comprise administering a pharmaceutical composition comprising a therapeutically effective amount of a corticosteroid.

US Patent No. 6,616,913 B1 - ("The '913 patent) Inventor - Mautone. The '913 patent discloses a method of increasing and enhancing eustachian tube lumen patency and pressure equalization performance by administering an aerosolized mixture of lipid crystals comprised of a mixture of one or more lipid surfactants and



or more spreading agents. Embodiments are disclosed wherein the mixture also comprises therapeutically active agents effective in the treatment of Otitis Media.

WO 97/29738 (Intl. app. no. PCT/US/02294 - ("The '294" application) The '294 application relates to methods of treating eustachian tube dysfunction using surfactants. In particular, it relates to the delivery of surfactants by inhalation to the eustachian tube to reduce its opening pressure.

WW 99/33472 (Intl. app. no. PCT/GB98/03526 - ("The '526 application") The 526 application relates to the treatment of serous otitis media and discloses a medicament comprised of a surface active phospholipid (SAPL) which is instilled as a powder into the middle ear.

The above-cited references are brought to the attention of the Examiner in conformance with 37 CFR 1.56 and 37 CFR 1.97 as they are deemed generally relevant to the subject matter of the present application. However, it is verily believed that said references, whether taken alone or in any combination whatsoever, do not anticipate, disclose, suggest or render obvious the present claimed invention. A copy of each of the above-cited patents is enclosed herewith for the Examiner's convenience and reference.

Respectfully Submitted,

34,445

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PTO/SB/08A (10-01)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/608,166
Filing Date	06/27/03
First Named Inventor	MAUTONE
Art Unit	1614
Examiner Name	Jagoe D.
Attorney Docket Number	

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of

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-4,814,161	03/21/99	Ajinks et. al.	Gen.
		US-4,895,719	01/23/90	Radherkrishnan	Gen.
		US-4,931,284	06/05/90	Ekman et. al.	Gen.
		US-4,973,465	11/27/90	Baurain et al.	Gen.
		US-5,004,611	04/02/91	Leigh	Gen.
		US-5,053,217	10/01/91	Lehigh	Gen.
		US-5,174,988	12/29/92	Mautone et al.	Gen.
		US-5,306,483	04/26/94	Mautone et al.	Gen.
		US-5,401,741	03/28/95	Sato et al.	Gen.
		US-5,470,587	11/28/95	Bartolmeo	Gen.
		US-6,001,870	12/14/99	Henkyl	Gen.
		US-6,093,417	07/25/00	Petrus	Gen.
		US-5,141,674	08/25/92	Leigh	Gen.
		US-6,156,294	12/05/00	Mautone	Gen.
		US-6,297,227	10/02/01	Johnson	Gen.
		US-6,616,913B1	09/09/03	Mautone	Gen.
		US-			
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ⁵
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		W097/29738	08/21/97	Nemechek	Gen.	
		W099/33472	07/08/99	Nemechek.	Gen.	

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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